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MESHING AROUND: LONG-TERM OUTCOMES FOLLOWING VAGINAL RECONSTRUCTIVE SURGERY WITH SYNTHETIC MESH AUGMENTATION

Hypothesis / aims of study
To characterize outcomes following vaginal reconstructive surgery with synthetic mesh augmentation 5-30 years following initial operation

Study design, materials and methods
This study involved a retrospective chart review along with invitation to participate in a cross-sectional written survey and pelvic examination. Data were collected from medical records, written surveys, and pelvic exams of patients who underwent vaginal surgery for pelvic organ prolapse with synthetic mesh augmentation between 1985 and 2010 at a single academic institution in the United States. Details regarding relevant past medical and surgical history, index surgery performed, intra- and post-operative complications, and relevant subsequent operations were abstracted from electronic and paper medical records. Eligible patients were invited by mail to complete a brief written survey and a focused pelvic exam. The written survey included demographic information, the Pelvic Floor Distress Inventory Short Form (PFDI-20), the Patient Global Impression of Improvement (PGI-I), and questions related to satisfaction and sexual function following the index operation, as well as complications and subsequent surgeries. Those participants who presented for pelvic examination were reimbursed $20 for transportation costs. Descriptive analyses were performed to characterize the sample. The primary outcome of interest was re-operation for mesh-related complication, and logistic regression was used to identify associated factors. Factors associated with mesh-related re-operation on univariate analysis with p-value less than .2 were included in the backward linear regression model. Secondary outcomes of interest included rates of specific mesh-related complications, overall reoperation rate, and current reported satisfaction with the index procedure.

Results
Among 804 potential patients identified, 161 patients were eligible for inclusion, with surgical dates ranging from May 1991 to October 2010. Of those 161 eligible patients, 43 (27%) have returned the written survey so far and 22 (14%) have completed a pelvic examination. Mean age at surgery was 60 years (SD11.6, range 31, 86) and mean BMI was 28.8 kg/m^2 (SD 5.6, range 19.4, 47.2). Seventy-nine percent (127/161) had undergone prior hysterectomy and 56% (90/161) previous prolapse repair. Table 1 describes the mesh placement for the 161 surgeries included in the chart review, of which 146 utilized macroporous, monofilamentous, non-absorbable mesh (type 1) and 9 (6%) involved a mesh kit.

Table 1. Surgical Information

	Overall	**Mesh**	**Extrusion/Erosion**
	n (%)	n (%)	n (%)
Anterior Colporrhaphy	106 (66)	84 (52)	19 (23)
Posterior Colporrhaphy	132 (82)	108 (67)	24 (22)
Apical Suspension	130 (81)	98 (61)	11 (11)
Uterosacral Suspension	115 (71)		
Sacrospinous Suspension	16 (10)		
Concomitant Hysterectomy	20 (12)		5 (25)

Overall, 33/161 (21%) women underwent mesh-related re-operation. Factors associated with re-operation for mesh-related complication are outlined in table 2. The most common indication for re-operation was vaginal mesh extrusion (n=25). The overall rate of mesh-related complication was 32% (52/161); 28% (45/161) had mesh extrusion into the vagina and 1% (2/161) had mesh erosion into the bladder (1) or rectum (1). Vaginal extrusions were treated with local estrogen (n=11), office excision (n=8), or surgical excision (n=25).

Table 2. Factors Associated with Reoperation for Mesh-Related Complication

	Re-operation	**No Re-operation**	**p-value**	**Adjusted Odds Ratio (95% CI, p-value)**
Age mean (SD)	54 (10.8)	62 (11.4)	.001	-.28 (-.017,-.004, p=.001)
BMI mean (SD)	27.5 (5.6)	29.2 (5.5)	.136	-.16 (-.027, .001, p=.063)
Prior prolapse repair	17 (52)	73 (57)	.569	
Prior hysterectomy	23 (70)	104 (80)	.147	Removed
Surgical Characteristics				
Anterior mesh	19 (79)	65 (77)	.853	
Posterior mesh	24 (86)	84 (81)	.547	
Apical mesh	31 (94)	99 (77)	.031	Removed
Concomitant hysterectomy	6 (18)	14 (11)	.261	
Wound complication	3 (9)	7 (6)	.442	
Perioperative Infection	9 (27)	39 (31)	.720	
Urinary tract injury	3 (9)	1 (1)	.006	Removed

The rate of reoperation overall was 31% (45/161); 33% (15/45) underwent more than one subsequent operation. Common indications for reoperation included mesh-related complication (n=33), subsequent pelvic organ prolapse (n=15), and urinary symptoms (n=9).

Among the 43 questionnaires received thus far, according to the PGI-I, 74% (n=32) are better, 9% (n=4) are the same, and 16% (n=7) are worse. When asked about level of satisfaction with surgery, 42% (18/43) reported being very satisfied, 28% (12/43) somewhat satisfied, 14% (6/43) somewhat unsatisfied, and 16% (7/43) very unsatisfied. Sixty-five percent (28/42) would definitely or probably do it again and 47% (20/43) would recommend it to someone else.

Interpretation of results

In this sample of 161 women who underwent vaginal reconstructive surgery with synthetic mesh augmentation between 7 and 26 years ago, more than 20% underwent re-operation related to their mesh, mostly for vaginal mesh extrusion, and younger age was associated with higher risk of reoperation on multivariate regression. Overall, almost one third of women underwent subsequent pelvic operation, and one-third of these women underwent more than one subsequent operation. Despite relatively high rates of improvement on the PGI-I, and 65% of women reporting that they would definitely or probably undergo the operation again, fewer than half would recommend it to someone else.

Concluding message

Rates of re-operation following pelvic reconstructive surgery with vaginal mesh placement are high over a time horizon of 25 years, but the majority of women remain satisfied with the operation. The overall reoperation rate may be as high as 30%, with younger women being more likely to undergo subsequent operation. We hope these findings can be used to inform pre-operative counseling of patients considering these procedures about long-term outcomes and risks of complications.

Disclosures

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